REMARKS

Applicants have canceled Claims 1-7 without prejudice in favor of new Claims 8-23. Support for the new claims is found in the originally filed claims and throughout the specification, especially the Figures and Exemplified embodiments. No new matter is believed to be introduced by the amendment.

At the outset, Applicants thank Examiner Becker for the suggestions provided during the discussions of the present application held on October 7, 2003, and anytime thereafter, which is summarized and expanded upon below. Further, Applicants thank Examiner Becker for indicating that the amendment above combined with the remarks below would appear to further favorable prosecution of the present invention. It should be noted that Applicants have amended the specification to properly identify the applications from which the present application claims the benefit of priority.

The objection to the specification is obviated by the submission of the Abstract attached hereto. Accordingly, withdrawal of this ground of objection is respectfully requested.

The objection to Claim 6 is obviated by the cancellation of this claim. Accordingly, withdrawal of this ground of objection is respectfully requested.

The rejection of the Claim 3 under 35 U.S.C. § 112, second paragraph, is believed to be obviated by the cancellation of this claim. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of the Claims 1-7 under 35 U.S.C. § 102(b) over Clark et al. is believed to be obviated by the cancellation of this claim. Accordingly, withdrawal of this ground of rejection is respectfully requested. Further, new Claims 8-23 are neither disclosed, nor suggested, by Clark et al. in light of the above amendment combined with the remarks below.

The present invention relates, in part, to a process for continuously reducing the presence of microorganisms in a liquid food product without denaturation by pressurizing a liquid food product; passing the liquid food product at least three times for time periods of the order of milliseconds for each through a continuous pressurizing circulating system at a non-denaturing temperature having within it a dynamic high pressure homogenizer; and collecting the liquid food product .

The Applicant has demonstrated in the present application that passing of a liquid at least three times through a dynamic high-pressure homogenizer, gives a more significant and a more consistent microbial elimination in the treated liquid. Results of Applicant itself also show that submitting a liquid only one time at a temperature of 25°C, and at a pressure of 100 Mpa (14 423 psi), equivalent conditions used in Clark et al., gives a reduction of microbial count of only 2 logs. However, when a liquid is treated at least three times (recirculated) even at a temperature of 25°C, and a pressure of 100 Mpa, the microbial activity is reduced by as much as 6 logs. A much higher killing effect is induced on microbes contained within the liquid when submitted to more than one passage of treatment with a dynamic high-pressure homogenizer (DHP).

In addition, Applicants have clearly described in page 15, lines 5 to 7 and 26-27 of the present application, that most of the bacteria show a rupture of the cell envelope due to the dynamic high pressure treatment and that the number of passes is also at least one outstanding factor affecting bacterial concentration.

Nowhere does Clark et al., disclose or suggest to re-circulate a treated liquid in a dynamic high-pressure homogenizer. Therefore, because of the absence of a clear description and/or suggestion, a person skilled in the art would recognize that, passing of a liquid at least three times through a dynamic high-pressure homogenizer, gives a more significant and a more consistent microbial elimination in the treated liquid due, in part, to breaking of the

microbial wall or membrane to kill such microbes. Further, the above-mentioned observations are neither disclosed nor suggested in Clark et al. On the contrary, Clark et al. describe only a reduction of microbial activity, which is different than reducing the number of microorganisms. In the present application, it is shown that submitting liquid food compositions to the dynamic high pressure homogenizer at least three times (which is by definition circulating liquid repetitively into a system applying dynamic high pressure on the food liquid composition) induces a sudden pressure drop, shear stress, cavitation and impeachment. All of these phenomena cause, in part, the cell disruption of microorganisms present in the liquid food composition.

Applicant would like to further bring to Examiner's attention that the subject matter presented in Clark et al. to support the claimed invention seems incoherent, or at least highly variable.

In Table 1 of Example 1 of Clark et al., it can be seen that the treatment of juice with the homogenizer at 15 000 psi allows a reduction of 55% only, reducing at 4200 CFU/ml at Day 0 when compared with the control group which is at 9300 CFU/ml. It can be observed also in this same table that the natural decrease of microbial activity in the case of the control group between Day 0 and Day 7 is of 83%. Moreover, microbial activity after 7 days in the case of the juice treated at 15 000 psi, is naturally (without further treatment after the first treatment) decreased by 98%, passing from 4200 CFU/ml to 200 CFU/ml. There is no difference in the microorganism's count, 200 CFU/ml in all cases, between treatments at 4 000, 9 500 and 15000 psi respectively at Day 7. That would mean that long term stability as claimed in Clark et al., by reduction of microorganism number is not better after high pressure homogenization treatment at 15 000 psi than at 4 000 psi, and almost not better than the control group in this example at all.

In addition, Clark et al. show in Table 2 of Experiment 1, that there are significant differences between experiments applying the same conditions of treatment. It is shown in this table that treatment of orange juice at 10 000 psi in experiment 1, creates a reduction in microbial activity of 28%, while in experiment 4, the reduction level is as high as 86%. After treatment of the orange juice at 15 000 psi, the microbial concentration is reduced by 76% in experiment 2, 91% in experiment 3, and 99% in experiment 5. In this Table, it can be seen that the reduction of microbial activity is of 1 or 2 logs only.

In direct contrast to Clark et al., the present application clearly demonstrates that passing the liquid food in the high pressure homogenizer at least three times yields a reduction of microbial number by as much as 6 logs.

Table 1 of the Example II in Clark et al. is the most puzzling demonstration proving the differential effect of different pressures in applying homogenization. One can see in Table 1 of Example II that microbial counts after treatment at 10 000 psi is reduced by 99.1%, passing from 550 000 CFU/ml to 5 100 CFU/ml, and not 91% as described in this Table. Additionally, microbial concentration after treatment at 15 000 psi is reduced by 99.5%, passing from 300 000 CFU/ml to 1 500 CFU/ml. There is no significant difference between treatments at both concentrations whatsoever.

In Example IV , microbial counts were lowered from $2,7 \times 10^5$ CFU/ml to 2.38×10^4 CFU/ml after treatment of grape juice at 15 000 psi, which is a reduction of 8.8% in microbial activity. This is a reduction of less than 1 log , and not of 91% . Therefore, considering the above noted details, one skilled in the art can clearly conclude that treating citrus juices by one passage, even during at least 1 minute, with high-pressure homogenization gives uncertain and significantly variable results and reduce their number.

One important element of the present invention is that the liquid to be treated is passed at least three times in the homogenizer. In Clark et al., no mention is made that more

than one passage may be conducted through the homogenizer, much less that such passage would exponentially reduces the microbial presence in the treated liquid. In addition to the high pressure, the liquid is submitted to high-pressure cavitation and velocity which are induced during the passage of the liquid through the valve. The latter generates the results shown in the present application: the microbial elimination is more significant and consistent than the one obtained by Clark et al. Even if the liquids are submitted to a single passage through the homogenizer at a high pressure of 15,000 psi during one minute, there is no evidence or it does not even remotely lead to the results obtained by passing the liquids at least three times in the homogenizers, as described in the present application.

In light of all of the above, the present invention presents results that can be neither disclosed or suggested by Clark et al., in that the skilled artisan could not have imagined that the particular steps of the method of the present invention would allow for a reliable reduction of microorganisms in a food liquid, much less that passage of such liquid at least three times through the homogenizer would result in such a superior reduction in microbes. Accordingly, Clark et al. clearly fails to disclose or suggest all limitations of the claimed invention

Clark et al. clearly fails to disclose or suggest all limitations of the claimed invention as required by the MPEP (see § 2143.03 and the enclosed copy of *In re Royka* 180 USPQ 580 (CCPA 1974)). Accordingly, Clark et al. clearly fails to anticipate the claimed invention, much less suggest it. Additionally, it has not been pointed out to the Applicants as to where any specific motivation lies within Clark et al. that would motivate the skilled artisan reading the same to modify the process disclosed therein towards the claimed invention.

In light of the above, it appears as if the Examiner is relying on the Applicants disclosure to supply motivation to modify the disclosure of Clark et al. to arrive at the claimed invention. However, this is clearly improper according to a recent decision

(enclosed) by the U.S. Federal Courts in In re Lee (61 USPQ2D 1430 (CA FC 2002)). The Lee Court indicated that the Office must provide specific motivation, hint, or suggestion, found in the references relied upon to support a *prima facia* case of obviousness. In the present case, the Office appears to rely on the present specification for motivation, which is clearly forbidden according to the Lee Court. In light of this decision, Applicants respectfully request the Office not to use the present specification as a guidepost to combine the disparate disclosures of the cited references (see the enclosed decision in In re Vaeck 20 USPQ 2d 1438).

In light of all of the above, Applicants respectfully request withdrawal of all grounds of rejection based upon Clark et al.

Should the Examiner believe that anything further is necessary in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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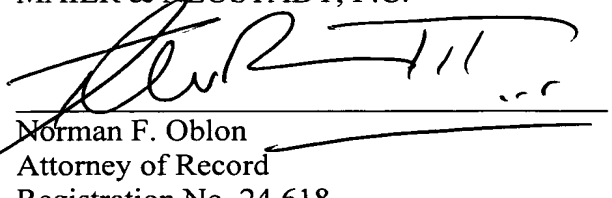

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